

U.S. Appln. S.N. 09/913,643
AMENDMENT AFTER FINAL REJECTION

PATENT

REMARKS

This Amendment cancels claims 20-23, rewrites claims 16 and 18 to depend from claim 34, and makes editorial changes to claims 30 and 32. Claims 16, 18, 19 and 24-34 are pending.

Examiner Fubara is thanked for the courtesies extended to the undersigned during a teleconference held May 31, 2005. Method claim 34 was discussed during the teleconference. No agreement was reached during the teleconference.

Examiner Fubara is also thanked for the courtesies extended to the undersigned during a personal interview held July 27, 2005. The Examiner Interview Summary Record accurately reflects the substance of the interview.

Entry of this Amendment is earnestly requested, as it is believed (1) to place the application in condition for allowance, (2) not to raise any new issue or require further search by the Examiner, (3) to be directly responsive to the Official Action and (4) to place the application in even better form for appeal, should such appeal be necessary. In this regard, the amendment of claims 16 and 18 to depend from claim 34 cannot raise a "new" issue because each of these claims was previously in the application.

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The editorial changes to claims 30 and 32 were suggested by the Examiner during the personal interview.

The 35 U.S.C. § 102(b) rejection of claims 24-34 over PCT Patent Publication WO 97/45367 to Ahola et al. is respectfully traversed. The distinguishing features of method claim 34 are discussed separately from the distinguishing features of fiber/delivery device/pharmaceutical preparation and method of administration claims 24-33.

1. Method Claim 34

A feature of method claim 34 is a correlation step in which the desired biodegradability of a silica fiber is correlated with the viscosity of a silica sol used to prepare the fiber. This correlation step requires one of ordinary skill in the art, seeking to prepare a silica fiber having a specific biodegradation rate, to correlate the desired biodegradability with a starting viscosity of the silica sol using a graph such as those illustrated in Figs. 8, 10 and 12. The required silica sol starting viscosity would be read from the graph, the silica sol prepared, and a fiber spun from the silica sol when the silica sol's viscosity reached a value correlating to the desired biodegradability of the silica fiber.

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During the interview the Examiner questioned whether the correlation step is a valid limitation. First, each word in a claim must be given weight. Second, a "correlation" step is a positive method step commonly found in U.S. patents. See, for example, claim 6 of U.S. Patent No. 6,922,580. Third, the correlation step distinguishes the claimed process from a hypothetical process in which a starting point viscosity is deliberately (or unconsciously) selected for any reason other than the purpose of achieving a desired biodegradability of the resulting silica fiber.

Ahola et al. utterly fails to disclose, teach or suggest the correlation step of claim 34. Reconsideration and withdrawal of the anticipation rejection of claim 34 over Ahola et al. are earnestly requested.

2. Claims 24-33

Claims 24-27 are directed to a delivery device and pharmaceutical preparation containing the controllably biodegradable silica fiber of claim 30. Claims 28 and 29 recite a method for administering a biologically active agent to a human or animal which employs a delivery device comprising a controllably biodegradable device of claim 30. Claims 30-33 are directed to a

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controllably biodegradable silica fiber spun from silica sol, a biodegradation rate of the fiber being adjusted by either controlling the starting point of the spinning process by a viscosity of the silica sol wherefrom the fiber is spun, or by controlling the viscosity of the spinning sol, the solubility of the fiber in simulated body fluid being 0.2 to 20 weight percent/hour.

Ahola et al. fails to expressly disclose (or suggest) biodegradable silica fibres having a solubility in simulated body fluid of 0.2 to 20 wt-%/h. Ahola et al. also fails to inherently disclose the claimed fibres because the reference fails to disclose the viscosity range employed to prepare these fibres.

The silica fibers' solubility in simulation body fluid of 0.2 to 20 wt-%/h is not an inherent property. This is demonstrated by the solubility values reported in Example 2 of Ahola et al. More particularly, silica fibers spun using a sol viscosity of approximately 10 mPas were put into aqueous solution within 48 hours and also four months later. Additional fibers were treated at 300°C and 700°C in addition to the fibers kept at room temperature. The fibers were dissolved in a simulated body fluid solution. Ahola et al. report that only fibers kept at room

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temperature dissolved in any significant amounts. Thus, fiber solubility is not an inherent property, but is instead determined at least partially by processing parameters such as heat treatment.

Ahola et al., also report that their room temperature fibers stored for four months dissolved by 10 wt-% within four weeks (Page 14, lines 19-20). Thus, the Ahola et al. silica fiber's¹ solubility in simulated body fluid is 0.0148 wt-%/h, which is significantly less than the 0.2 to 20 wt-%/h solubility required by the applicants' claims.

Reconsideration and withdrawal of the anticipation rejection of claims 24-33 over Ahola et al. are earnestly requested.

The 35 U.S.C. § 103(a) rejection of claims 16 and 18-34 over German patent DE 196 09 551 ("German '551") is respectfully traversed. The distinguishing features of method claims 34, 16, 18 and 19 are discussed separately from the distinguishing features of

¹Examples 6 and 8 of Ahola et al. both use a recipe (TEOS, H₂O and acetic acid in a molar ratio of 1:14.2:0.5) which produces a sol that cannot be drawn into fiber. One of ordinary skill in the art would know that fibers cannot be drawn from silica sols having a H₂O/Si molar ratio greater than 2. See, e.g., Brinker et al., "Spinnability of Silica Sol," 111 Journal of Non-Crystalline Solids 48-54 (1989) and Section 2.6.6 of Brinker et al., Sol-Gel Science: The Physics and Chemistry of the Sol-Gel Processing 203-209 (1990) (copies attached).

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the fiber/delivery device/pharmaceutical composition and method of treatment claims 24-33.

1. Method Claims 34, 16, 18 and 19

A feature of method claim 34 is the correlation of a desired biodegradability of a silica fiber with the viscosity of a silica sol to determine when the spinning process should begin. The applicants have unexpectedly discovered that the biodegradability of a silica fiber can be controlled, i.e., determined, by controlling the starting point of fiber spinning based upon the viscosity of the silica sol (Specification, page 2, lines 25-28).

German '551 fails to disclose or suggest that one of ordinary skill in the art, seeking to prepare a silica fiber having a particular biodegradation rate, could achieve the desired biodegradation rate by controlling the starting point of fiber spinning based upon the viscosity of the silica sol. Reconsideration and withdrawal of the obviousness rejection of claims 34, 16 and 18-20 over German '551 are earnestly requested.

2. Fiber/Delivery Device/Pharmaceutical Composition Claims 24-33

As previously discussed, a feature of claims 24-33 is a biodegradable silica fiber having a solubility in simulated body fluid of from 0.2 to 20 wt-%/h.

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German '551 fails to raise a *prima facie* case of obviousness against the claimed fiber (and delivery device, pharmaceutical composition and method of treatment based thereon) because this reference fails to disclose or suggest the solubility range required by the claimed fiber (which will result in complete fiber dissolution in about 21 days for the lower (slower) dissolution range limit). In contrast, German '551 discloses a fiber whose fastest dissolution time is 50 days.

The Patent Office argues the claims do not recite how long it takes the fiber to dissolve. However, the claimed fiber patentably distinguishes the German '551 fiber based on its fiber solubility range of 0.2 to 20 wt-%/h. No other limitation is required. That the product claims do not recite concentration limits, the amount of silica sol, or how long it takes the fiber to dissolve, is immaterial.

The Patent Office questions why the difference in dissolution times (21 days vs. 50 days) would be considered unexpected or surprising to one of ordinary skill in the art. The answer is that silica fibers with such fast dissolution times simply had not been achieved by the methods of the prior art. One or ordinary skill in

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the art would not have believed silica fibers with such a fast dissolution rate (0.2 to 20 wt-%/h) could be prepared.

Fibers with fast or very fast dissolution rates can be used for different applications. In tissue engineering and guiding applications it can be very important that the fiber dissolves rather quickly. In such applications support for cell growth is needed for a specific time only; after that limited time undissolved fiber can hinder the desired path of cell growth and thus be a hindrance. Fast dissolution rates are also advantageous in many delivery device applications in which a specific agent is delivered for a period of one or two weeks or even a shorter time period. In such devices the agent is delivered through dissolution of the fiber and thus dissolution time equal to the intended/desired delivery period is of utmost importance.

Reconsideration and withdrawal of the obviousness rejection of claims 24-33 over German '551 are earnestly requested.

It is believed this application is in condition for allowance. Reconsideration and withdrawal of all rejections of claims 16 and 18-34, and issuance of a Notice of Allowance directed to claims 16, 18, 19 and 24-34, are earnestly requested. The Examiner is urged

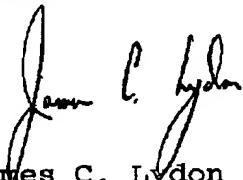
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to telephone the undersigned should she believe any further action
is required for allowance.

A Petition and fee for a two month Extension of Time are
attached. It is not believed any additional fee is required for
entry and consideration of this Amendment. Nevertheless, the
Commissioner is authorized to charge our Deposit Account No. 50-
1258 in the amount of any such required fee.

Respectfully submitted,



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Enclosures:

Petition for Extension of Time
Brinker et al., 111 J. Non-Crystalline Solids 48-54 (1989)
Section 2.6.6 of Brinker et al., Sol-Gel Science: The Physics
and Chemistry of the Sol-Gel Processing 203-209 (1990)